K001961

JAN 2 5 2001

510(k) Summary

SUBMITTER:
Stockert Instrumente GmbH
Division of Sorin Biomedica SpA
Lilienthalalle 5-7
D-80939 Munich Germany

APPLICANT:
COBE Cardiovascular, Inc.
Division of Sorin Biomedica SpA
14401 W. 65th Way
Arvada, Colorado 80004-3599 USA

CONTACT PERSON:
Lynne Leonard
Regulatory Affairs Manager
COBE Cardiovascular, Inc.
Arvada, Colorado USA
Phone: (303) 467-6586
Fax: (303) 467-6429

DATE PREPARED:
March 1, 2000

DEVICE TRADE NAME:
Stockert A242 and A252 Series Arterial Femoral Cannulae

COMMON/USUAL NAME:
Cardiovascular Femoral Cannulae

CLASSIFICATION NAME:
Cardiopulmonary Bypass Vascular Catheter, Cannula or Tubing

PREDICATE DEVICE:
Baxter Research Medical Inc. Fem-Flex Wire Reinforced Arterial Femoral Cannulae

DEVICE DESCRIPTION:

The Stockert A242 and A252 Series Arterial Femoral Cannulae are sterile, non-pyrogenic devices, for single use only, and are not to be resterilized by the user. The devices are polyvinyl chloride (PVC) wire reinforced arterial femoral cannulae with a straight tip. They are intended to be used to cannulate the arterial vessels during cardiopulmonary bypass surgery. During use, the cannula is inserted into the arteria femoralis, allowing oxygenated blood from the extracorporeal circuit to re-enter the systemic circulation. Insertion of the cannula into the arteria femoralis during cardiopulmonary bypass surgery is an alternative method for the insertion of a cannula into the arterial system.

The Stockert A242 Series cannulae are 22 cm in length and 16 Fr to 22 Fr in diameter, with a luer port and connector that accepts 3/8" tubing. The A252 Series cannulae are 19.5 cm in length and 9 Fr to 21 Fr in diameter, with a luer port and connector that accepts 1/4" tubing (the 16 Fr - 21 Fr sizes have a reducing connector that accepts either 1/4" or 3/8" tubing).

The devices are comprised of three components, the cannula tube, the cannula tip, and the connector. Encapsulated within the cannula outer wall is a helically wound stainless steel wire for kink resistance.

INDICATIONS FOR USE

The Stockert A242 and A252 Series Arterial Femoral Cannulae are intended to be used for cannulating the femoral arterial vessels during cardiopulmonary bypass surgery.

STATEMENT OF TECHNICAL CHARACTERISTICS COMPARISON

The Stockert A242 and A252 Series Arterial Femoral Cannulae are substantially equivalent to the Baxter Research Medical Inc. Fem-Flex Wire Reinforced Arterial Femoral Cannulae.

The following tests were performed to demonstrate equivalency of the devices:

1. Pressure Drop
2. Blood Trauma
3. Leak
4. Kink Resistance
5. Bond Strength
6. Dimensional Inspection Post-sterilization and Post-aging

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 5 2001

Ms. Lynne Leonard
Regulatory Affairs Manager
Stockert Instrumente GmbH
C/O COBE Cardiovascular, Inc.
14401 W. 65th Way
Arvada, CO 80004-3599

Re: K001961
Trade Name: Stockert A242 and A252 Series Arterial Femoral Cannulae
Regulatory Class: II (two)
Product Code: 74 DWF
Dated: November 2, 2000
Received: November 7, 2000

Dear Ms. Leonard:

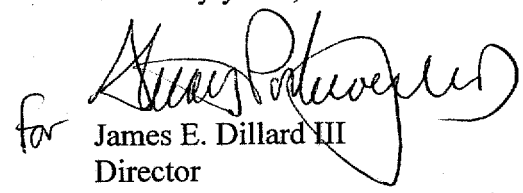
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (If known): _____

Device Name:

Stockert A242 and A252 Series Arterial Femoral Cannulae

Indications For Use:

The Stockert A242 and A252 Series Arterial Femoral Cannulae are intended to be used to cannulate the femoral arterial vessels, via access into the arteria femoralis, during cardiopulmonary surgery for periods of up to six hours.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K001961

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

1-24-1

Division of Cardiovascular & Respiratory Devices
510(k) Number K001961